

**REMARKS****Claim Amendments**

Claims 1 and 20 have been amended to specify the length of the member as extending substantially along the length of the piston. Also, claims 1, 17, 19, 20, and 34 have been amended to specify that an electrical potential is applied to the member. Finally, claims 20 and 34 have been further amended to correct a typographical error.

**Claim Rejection 35 U.S.C. § 102(b)**

The Examiner rejected claims 1-2, 5-10, 20 and 28-33 under 35 U.S.C. § 102(b) as being anticipated by Nason et al (U.S. Patent Number 6375638). Additionally, the Examiner rejected claims 1-4, 11, 20, and 22-23 under 35 U.S.C. § 102(b) as being anticipated by Venditti et al (US Patent No. 2928390). Before addressing specific claim rejections, a brief description of one embodiment of the invention is provided without limitation of the claims.

A drug injector includes a chamber for holding a drug to be injected into a biological body, and a nozzle through which the drug is injected. A piston is positioned in the chamber, and an actuator is coupled to the piston. The actuator includes a member such as a shape memory alloy that contracts when heated. In some embodiments, heating of the member is induced by applying an electrical potential to the member. The actuator moves the piston towards the nozzle when the member is heated to expel the drug out of the chamber through the nozzle. The drug injector can include a sensor for measuring properties of the outer layer of the body and can adjust the piston movement based on the sensed properties.

Turning briefly to the first cited reference, Nason describes a drive mechanism for an incremental medication delivery device. The drive mechanism includes a force receiving member, a force applying member, and a shape memory alloy actuator.

Claim 1 recites an actuator including a member that contracts when a potential is applied to the member, and has been amended to clarify that the potential is an electrical potential. Additional, the length of the member in relation to the piston and chamber is emphasized by the amendment of Claim 1, which now reads “an actuator including a member that contracts when an electrical potential is applied to the member, the member extending substantially along the length

of the piston and the chamber..." The length of the member in relation to the piston and chamber is shown in Figures 1A-1B.

The Nason patent describes an incremental motion pump mechanism which is powered by a shape memory alloy actuator. The shape memory member 30 is located only within the actuator as shown in Figure 3, and described in column V, lines 32-66 to column VI, lines 1-35. The shape memory member does not extend substantially along the length of the piston as described in amended base Claim 1, and is thus unable to drive the piston a full stroke.

The length of the member additionally relates to the mechanism by which the medication is released. Nason describes a drive medication that incrementally releases the medication due to the shape memory alloy driving a pawl mechanism. (Nason, Col. V, lines 56-64.) Applicant's device does not release the medication incrementally, but in one quick release as a result of the location of the member along the length of the piston. The contraction of the member when a potential is applied to the member, causes the piston to release the medication from the chamber in one quick pulse. This can be better understood by looking at page 7, lines 26-29 to page 8, line 1-16.

Claims 2 and 5-10 depend either directly or indirectly from amended base Claim 1 and therefore contain all the elements of that base claim. Therefore, each of these claims is allowable for the same reasons argued above.

Rejected base Claim 20 has also been amended to include a similar limitation specifying the length of the member as in amended base Claim 1, and is therefore allowable with respect to Nason for the same reasons as argued above. Rejected claims 28-33 depend either directly or indirectly from amended base claim 20 and therefore contain all the elements of that base claim. Therefore, each of these claims is allowable for the same reasons argued above.

As previously stated, the Examiner has also rejected claims 1-4, 11, 20, and 22-23 as anticipated by Venditty. Venditty describes a needleless multi-dose hypodermic injector which is operated hydraulically. The Examiner has stated that Venditty describes an actuator that moves the piston towards the nozzle when a potential is applied to the member, a spring. Venditty describes a "fluid tight chamber which receives hydraulic fluid" from a tube for compressing the spring and thus driving the piston forward to expel the medicament. (Venditty, Col. V, lines 66-73.) An electrical potential, is therefore, not applied to the spring causing it to the compress as

recited in Applicant's amended base Claims 1 and 20. The spring is compressed by hydraulic pressure. (Venditty, Col. VII, lines 56-66.)

Additionally, the member or spring does not extend substantially along the length of the piston, as recited in amended base Claims 1 and 20. Further, rejected Claims 2-4, and 11 depend either directly or indirectly from amended base claim 1, while rejected Claims 22-23 depend either directly or indirectly from amended base claim 20, and are therefore allowable for the same reasons as argued above.

In order to reject a claim under 35 U.S.C. §102(b), the reference must teach each and every element of the claim. As stated by the Federal Circuit, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. §2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Accordingly, Applicant submits that base Claims 1 and 20 as amended herein are not anticipated, because the references do not teach each and every aspect of the claimed invention. Claim 2-10, 22, 23 and 28-33 depend either directly or indirectly from amended base Claims 1 or 20 and therefore contain all the elements of those base Claims. Applicants respectfully request that the Examiner reconsider and withdraw the §102(b) rejection of these claims.

Rejection 35 U.S.C. § 103(a)

The Examiner rejected Claims 5-10 and 28-33 under 35. U.S.C. 103(a) as being unpatentable over Venditty in view of Flahery et al (US Patent No. 6656159B2 and 6723072B2); Claims 12 and 24 under 35. U.S.C. 103(a) as being unpatentable over Venditty in view of Smoliariv et al (U.S. Patent No. 6626871B1); Claims 13 and 25 under 35. U.S.C. 103(a) as being unpatentable over Venditty in view of Smoliariv in further view of Henderson (US Patent No. 3574431) or Gaide et al (US Pub No. 2002/014364A1); Claims 14-15 and 26-27 under 35. U.S.C. 103(a) as being unpatentable over Venditty in view of D'Antonio (US Patent No. 5318522); Claim 16 under 35. U.S.C. 103(a) as being unpatentable over Venditty in view of Hagen (US Patent No. 5354273); Claims 17-18 and 34-35 under 35. U.S.C. 103(a) as being unpatentable over Venditty in view of Flaherty; Claim 19 under 35. U.S.C. 103(a) as being

unpatentable over Venditty in view of Flaherty in further view of Hagen; and claim 21 under 35 U.S.C. 103(a) as being unpatentable over Venditty or Nason.

In order to reject a claim under 35 U.S.C. §103(a), the Office Action must first establish a *prima facie* case of obviousness. Establishing a *prima facie* case of obviousness requires that: (I) there must be some suggestion or motivation, either in the reference or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (ii) there must be a reasonable expectation of success; and (iii) the prior art reference must teach or suggest all of the claim limitations. *In re Vaeck*, 947 F2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The Venditty patent has been described above while addressing the 102(b) rejection by the Examiner. Independent claims 1 and 20 have been amended to specify the length of the member, as extending substantially along the length of the piston. Venditty, as discussed with regard to the 102(b) rejection, does not teach or suggest this limitation. Additionally, Venditty does not teach or suggest applying an electrical potential to a member causing it to contract, but applies hydraulic pressure to a spring causing it to compress.

Claims 5-10, 12, 13, 14-15, and 16 rejected by Examiner under 35 U.S.C. 103(a) depend directly or indirectly on amended base Claim 1, while Claims 21, 24, 25-27, and 28-33 depend directly or indirectly on amended base Claim 20 and therefore include all of the limitations of those claims.

Since Venditty does not teach, suggest, or otherwise provide motivation for the Independent Claims 1 and 20, the dependent Claims should be allowable under 35 U.S.C. 103(a) against Venditty for at least the same reasons. Some specific references and rejections will, however, be addressed below.

The Examiner has rejected claims 5-10, and 28-33 over Venditty in view of Flaherty. Flaherty describes a device for delivering fluid to a patient. The device includes a plunger assembly 240 including a shape memory element 242 connecting first and second lateral elements, respectively 200 and 220, and having a changeable length decreasing from a charged length to an uncharged length. (Flaherty, US Patent No. 6,723,072B2, Fig. 2, Col. VII, lines 19-67.) Like the previously described Nason reference, Flaherty does not describe a member that extends substantially along the length of the piston as recited in amended base claims 1 and 20, and only provides for incremental movement.

The Examiner has rejected independent Claims 17 and 34 and dependant Claims 18 and 35 over Venditty in view of Flaherty. Venditty, as stated previously, does not motivate, teach or suggest an electrical potential being applied to a shape memory alloy actuator, causing its contraction. Venditty describes a spring which compresses under hydraulic pressure. Additionally, Venditty does not motivate, teach, or suggest positioning a drug vial in a housing that has a nozzle through which the drug is injected to expel the drug from the nozzle as stated in amended Claims 17 and 34. The Examiner has referred to a container 44 as a vial. The vial 44 does not have a nozzle through which the medicament is actually injected into the skin, but is simply used to fill a chamber so it can further be injected. ( Venditty, Col. IV., lines 20-30.) Flaherty also does not describe a vial which has a nozzle through which a drug is injected. Flaherty describes a reservoir 230 connected to an exit port assembly 70 through which the medicament is expelled. (Flaherty, US 6,723,072, Col. VI, lines 23-31.) The combination of Venditty and Flaherty, therefore, does not teach or suggest all of the claim limitations in base claims 17 and 34 and therefore respectively dependant claims 18 and 35.

The Examiner also rejected Independent claim 19 over Venditty in view of Flaherty and in further view of Hagen. Hagen describes a delivery apparatus for delivering a medicament from a delivery device in which the delivery pressure is automatically regulated at a preselected level. The pressure of the delivery can also be adjusted according to sensed skin temperature. For the same reasons as stated in addressing the 103(a) rejection of base claim 34, Venditty and Flaherty do not teach or suggest the limitations of applying an electrical potential to a shape memory alloy member, and of expelling a drug out of the "the nozzle of the vial" as stated in claim 19. The combination of Venditty, Flaherty, and Hagen, therefore, do not teach or suggest all of the claim limitations of independent Claim 19.

Accordingly, Applicants submit that all of the claims are patentable and respectfully request that the Examiner reconsider and withdraw the rejections.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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